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## YALE LAW & POLICY REVIEW

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### If We Only Knew What We Know: Open Regulatory Review at the FDA

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#### INTRODUCTION

When the Air Force was struggling with the problem of pilots and civilians dying because of unusual soil and dirt conditions in Afghanistan, it did not know where to turn to get help quickly. The soil was getting into the rotors of its Sikorsky UH-60 helicopters and obscuring the view of its pilots—what the military calls a “brown out.” Ironically, the policymaker tasked with addressing the problem in the Department of Defense (DOD) had no way to know that the man practically sitting across from him had nine years of experience flying these Blackhawk helicopters in the field. Civil service titles, such as “director” and “assistant director,” reveal little about skills or experience.

In the fall of 2008, the Air Force Research Lab (AFRL) piloted Aristotle, a first-of-its-kind-in-government expert search-and-discovery software platform aimed at increasing collaboration and expert awareness across the DOD’s agencies. Expert discovery, also called “people search” or “expert networking,” refers to software with algorithms that make it easier to sort people based upon criteria such as reputation, credentials, skills, and experience. There is nothing magical here. The need to segment an audience is a commonly encountered problem, especially in online advertising.

Aristotle was a searchable internal directory that algorithmically integrated people’s credentials and experience from existing personnel systems, public databases, and from users themselves. This made it easy to quickly discover who knew what and who had done what. Although it was believed to be capable of

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saving the government money over the long term<sup>1</sup> due to its ability to locate and use in-house expertise, near-term budgetary constraints killed the project in 2013.

Ultimately, the real failure of Aristotle lay not in its demise but in the failure of government to learn from the experience. The project could have yielded powerful insights about the value of such a system for collaboration and performance at the Defense Department. At a more granular level, it might have shown whether searching for and targeting requests to participate in an activity based on a person's expertise, rather than simply posting an open call for engagement, does more to improve collaborative problem solving across a bureaucracy.

Aristotle was an attempt to solve a challenge faced by every agency and organization: quickly locating expertise to solve a problem. Prior to Aristotle, the DOD had no coordinated mechanism for identifying expertise across its two hundred thousand employees, which led to a gap in knowing what knowledge actually existed within the DOD or where to find it. Dr. Alok Das, the Senior Scientist for Design Innovation who was tasked with implementing the system, explained simply that "[w]e don't know what we don't know."

This is a common situation. Policymakers often lack clear, cost-effective, and reliable ways to leverage the full range of expertise potentially available to them—"the wisdom of the crowd." This reinforces the traditional pattern of the government operating behind closed doors with decisionmaking conducted only by professionals in the relevant department or agency. The problem, of course, is that these professionals don't have all the answers. Philip Tetlock deepened this observation in his book *Expert Political Judgment*, in which he described empirical research assessing professional political predictions against performance benchmarks. He found few signs that professionals possess "greater ability to make either 'well-calibrated' or 'discriminating' forecasts"<sup>2</sup> than regular citizens (or a monkey, for that matter).

It is no surprise, therefore, that the use of crowdsourcing is on the rise in government. Nor is it a surprise that mastery of these open-call techniques is still a work in progress. The government currently has no systematic way of quickly getting help from all those with relevant expertise, experience, and passion who, if asked, would volunteer their time to tackle pressing public challenges. For every success on Challenge.gov, the federal government's platform where agencies post open calls to solve problems, there are another dozen open-call projects that never get seen by those who might have the relevant insights or experiences to help—even when the calls are accompanied by a prize. Participation through

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1. Alton Hoover, *Aristotle—A Social Networking Solution Designed and Built for the Air Force Research Laboratory*, 2008 AEROSPACE & ELECTRONICS CONF. 36, 36; see *The Defense Technical Information Center (DTIC): Aristotle Launched*, DEF. THREAT REDUCTION AGENCY (Aug. 6, 2010), <http://www.dtra.mil/News/Multimedia/NewsArticle9.aspx>; Open Gov't Initiative, *Aristotle*, THE WHITE HOUSE, <http://www.whitehouse.gov/open/innovations/Dod-Aristotle> (last visited Apr. 18, 2014).
  2. PHILIP E. TETLOCK, *EXPERT POLITICAL JUDGMENT: HOW GOOD IS IT? HOW CAN WE KNOW?* 20 (2005).

crowdsourcing is still too ad hoc, infrequent, and unpredictable to provide a reliable basis for policymaking.

Prize-backed challenges work best when there is a big enough “haystack” and an enticing enough monetary purse to coax out the “needle.” While social media and prizes accelerate the opportunity to participate, they are not fast, systematic, or reliable enough to affect how decisions get made or how problems are solved. We have not stopped making policy in traditional ways because crowdsourcing, by itself, relies too much on hit-or-miss serendipity. The high costs of finding the right expertise means we have to continue to rely solely on professionals for governing.

Technologies like Aristotle are exciting because they increase the number of needles policymakers will find by making expertise searchable and discoverable. This has the potential to lower the costs of finding relevant expertise faster—and to enable those with expertise to identify the challenges. There is a dual benefit here: expert networks accelerate the search for innovative solutions to hard problems and foster greater citizen engagement.

Expert networks can help with finding and attracting more diverse expertise to tackle problems. It is high time to examine whether it is possible to enhance the intelligence of public institutions by targeting people on the basis of their credentials, skills, or experience; by making them more aware of the opportunity to participate; or by facilitating the process of matching expertise to public problems. I examine below, in some detail, a new experiment in expert networking at the Food and Drug Administration (FDA). The agency is turning to expert networking tools akin to Aristotle to find needed expertise within the agency in the first phase. Subsequently, the approach will be rolled out across the Department of Health and Human Services (HHS) and among the public to improve the regulatory review of medical devices. In its first phase, the project will target internal experts to provide technical advice to regulatory review panels. In the second phase, the project will move on to recruiting external experts to staff those review panels. This is an important project because, in this arena, high-quality and diverse expertise is desperately needed to protect citizens and accelerate the path of new devices to market.

Important as the regulatory review problem is, however, and as striking as this experiment seems, there is something missing. Absent is a comparable level of attention to using these initiatives as focused experiments to learn how to locate experts better and with more and more precision. Not enough is reliably known about which approaches work better in which contexts. If new expert network initiatives do not include experimental research designs from the outset, the government will never learn enough to scale effectively.

## I. EXPERTNET: A STALLED ATTEMPT AT TARGETING EXPERTISE

In the first (2011)<sup>3</sup> and second (2013)<sup>4</sup> United States Open Government National Action Plans—the written commitments to institutional innovation required of each country belonging to the global Open Government Partnership—the Obama Administration implemented the President’s promise from his Presidential Memorandum on Transparency and Open Government. This Memorandum called for engaging the knowledge, expertise, and perspectives of diverse members of the public. As President Obama has said, “knowledge is widely dispersed in society, and public officials benefit from having access to that dispersed knowledge” and hence to “collective expertise and wisdom.”<sup>5</sup>

Dubbed the ExpertNet Project,<sup>6</sup> the White House endeavored to make good on the President’s promise by launching an online discussion via a wiki about the desired features of new engagement platforms. The White House ExpertNet wiki specifically solicited input about platforms and processes for targeting and matching public expertise to opportunities to participate:

The Department of Innovation (the “officials”) wants informed, public input on the department goal of improving the literacy and mathematical skills of adults seeking advancement. Among the questions they want to ask are:

- What empirical evidence exists about the relationship between adult academic performance/career advancement and incentives and the impact of the structure of the incentive—whether explicit or implicit, predictable or unpredictable, tangible or intangible, etc.—on the outcomes?
- What visualizations help to illustrate the relationship between academic performance and incentives?
- What are the methods of identifying incentives to which adult learners will respond, while taking into consideration key causal criteria that might affect incentive effect (e.g., ethnic and family wealth differences that might influence attractiveness of different incentives) and unwanted side effects?

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3. Open Gov’t P’ship, *National Action Plan for the United States of America*, THE WHITE HOUSE (2011), [http://www.whitehouse.gov/sites/default/files/us\\_national\\_action\\_plan\\_final\\_2.pdf](http://www.whitehouse.gov/sites/default/files/us_national_action_plan_final_2.pdf).
  4. Open Gov’t P’ship, *Second Open Government National Action Plan for the United States of America*, THE WHITE HOUSE (2013), [http://www.whitehouse.gov/sites/default/files/docs/us\\_national\\_action\\_plan\\_6p.pdf](http://www.whitehouse.gov/sites/default/files/docs/us_national_action_plan_6p.pdf).
  5. Memorandum on Transparency and Open Government from President Barack Obama to the Heads of Exec. Dep’ts and Agencies (Jan. 21, 2009), [http://www.whitehouse.gov/the\\_press\\_office/TransparencyandOpenGovernment](http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment).
  6. *ExpertNet: Getting Started*, EXPERTNET, <http://expertnet.wikispaces.com/Getting+Started> (last accessed Apr. 18, 2014).

- What specific information should the Department of Innovation collect in order to identify those best suited to invite to test the program?
- What best practices could be leveraged from the public or private sector, and what is the evidence that they work?<sup>7</sup>

The ExpertNet proposal, which I authored, sought public input about the platforms, techniques, and processes available for discovering expertise, including tools designed to do expertise searching, process refinements needed to use expertise better, examples of others using expert discovery, and any legal or other impediments. The ExpertNet conversation attracted advice from forty-two registered users, including professors from a range of universities from MIT to Maryland, industry experts, and activists. The intention was to learn from that advice by running pilot projects to test the suggested strategies using different platforms and seeing what worked.

But the project stalled because of the absence of a senior government official willing to ask a question and admit to not having all the answers.

## II. THE SECOND GENERATION OF EXPERTNET: FROM THEORY TO PRACTICE AT THE FOOD AND DRUG ADMINISTRATION

Now, several years later, the FDA is starting to fulfill the promise of ExpertNet by going beyond hypotheticals to experiment with *targeting* expertise in practice. The FDA is accomplishing this goal by using a new and custom-built platform for cataloging and searching experts to identify those who might be in the best position to offer useful insights.

Among its important responsibilities, the FDA is tasked with reviewing the efficacy and safety of new medical devices, which include a range of products—from Band-Aids to heart stents—that reduce suffering, extend lives, treat diseases, and generate enormous economic gain for successful inventors. The Center for Devices and Radiological Health (CDRH), a division of the FDA, manages this complex process of premarket approval and post-market review of all medical devices. CDRH's Office of Science and Engineering Laboratories (OSEL), its research hub, employs its own scientists and also consults with outside experts whose job it is to understand the safety and efficacy of medical devices.

While the pathway to regulatory review and compliance for low-risk items like tongue depressors is straightforward, more complex, life-sustaining, or high-risk devices such as pacemakers and breast implants require judicious premarket approval by those with the right know-how within an appropriate time frame. If these medical devices reach patients prior to being properly tested, there may well be very real human costs. Dr. Steven Nissen of the Cleveland Clinic estimates that faulty devices contributed to more than 2,800 deaths in 2006 alone.<sup>8</sup> In a CBS

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7. *Id.*

8. Diana M. Zuckerman, Paul Brown & Steven E. Nissen, *Medical Device Recalls and the FDA Approval Process*, 171 ARCHIVES INTERNAL MED. 1006 (2011).

report on medical implants, Dr. Nissen noted that “people make the assumption that when their doctor implants a device, whether it be an artificial joint or a pacemaker, that it’s undergone very rigorous testing. That assumption isn’t always true.”<sup>9</sup> From breast implants to metal hip replacements, there have been recalls impacting thousands of people.<sup>10</sup> Improving pre-market approval does not address the need for post-market vigilance to identify dangerous and faulty devices before extensive harm can occur.

### III. THE EXPERTISE DEFICITS IN REGULATORY REVIEW

In the current model of pre-market review, several challenges exist, including a shortage of agility, expertise, diversity, and complexity.

#### A. Agility Deficit

Premarket review and approval is designed to protect consumers, but it should also accelerate the path to market for potentially life-saving and lucrative tools. At present, however, it can take nine months simply to find and convene a qualified review panel. As the FDA itself explains:

Millions of Americans rely on the FDA to approve life changing drugs and devices. These innovative medical devices and drugs reduce suffering, extend lives, and treat previously untreatable conditions to the benefit of our Citizens. The FDA has long been criticized for being too slow in approving medical innovation. Part of the criticism stems from not bringing the right expertise into review cycles at the right time. Yet, one of the biggest challenges is finding the right experts at the right time especially now that science, technology, software, infrastructure and other disciplines are colliding. We have a surge of mobile health devices expected to come into the FDA, more combinatorial products, more large molecules, nano-delivery systems and many more innovative approaches that require cross-disciplinary expertise.”

Only 100 scientists work at OSEL (800 total at CDRH), and there is always a need to get more expertise. The staff at CDRH also has to stay on top of the safety of devices throughout their lifecycle, which creates further burdens. This partly

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9. Elaine Quijano, *Report: Medical Implants Rarely Tested*, CBS NEWS, Mar. 28, 2012, [http://www.cbsnews.com/8301-505269\\_162-57405666/report-medical-implants-rarely-tested](http://www.cbsnews.com/8301-505269_162-57405666/report-medical-implants-rarely-tested).
  10. See, e.g., Greg Farrell & David Voreacos, *J&J Hip Failure Rate as High as 49 Percent, U.K. Doctors Say*, BLOOMBERG NEWS, Mar. 9, 2011, <http://www.bloomberg.com/news/2011-03-09/j-j-hip-replacement-failure-rate-may-be-49-u-k-orthopedists-group-says.html>.
  11. Jessica Nadine Hernandez, Office of Science and Engineering Laboratories, Food and Drug Administration (2013) (unpublished draft blog posting) (on file with author).

explains why, from 2000 to 2010, the average time to decision on high-risk but potentially life-saving devices increased by nearly 60 percent (from 96 to 153 days). Over approximately the same time period (2000 to 2009), the number of submissions for pre-market approval remained the same, hovering just below 10,000 (9,594 in 2000 and 9,655 in 2009).<sup>12</sup> To remedy the deficit, the FDA has instituted new information-technology decision-support tools. The FDA has also adopted a policy of giving clearer guidance about the necessary steps, including key scientific and regulatory requirements, that need to be satisfied within a 120-day period. But in order to map out a more predictable yet customized regulatory pathway, the FDA needs more expertise faster, including more internal expertise to advise regulatory review panels. Budget cuts make it difficult to hire more knowledgeable regulatory review staff.<sup>13</sup>

### B. Expertise Deficit

In January 2011, the FDA committed to a plan of action known as the Innovation Pathway to transform its regulatory process and improve how it works with entrepreneurs both to bring new devices to market and to protect the public. But to modernize the regulatory review process and help the agency keep up with the increasing complexity of devices, the agency needs better expertise faster.<sup>14</sup> The Innovation Pathway pinpointed the expertise deficit as a key problem, citing the need for greater collaboration with a network of experts.<sup>15</sup> In fact, CDRH

already uses outside experts for its advisory panels. But panel membership is limited to a pool of Special Government Employees who must be recruited and enrolled. The Center cannot be assured that an expert in an emerging technology will be available when that expertise is needed. Other traditional sources of external expertise, such as public workshops, conferences and literature may lag behind current research or may not be available when a scientific question arises at CDRH.<sup>16</sup>

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12. Office of Device Evaluation, *Annual Performance Report: Fiscal Year 2009*, U.S. FOOD & DRUG ADMIN. 4 (2009), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM223893.pdf>.
  13. See Susan Jaffe, *FDA Reforms Hampered by Budget Freeze*, 380 LANCET 1458, 1458-59 (2012).
  14. See *Innovation Pathway*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/default.htm> (last updated Mar. 10, 2014).
  15. See *CDRH Network of Experts*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm289534.htm> (last updated Mar. 7, 2014).
  16. *FDA Outlines Plans for an Outside Network of Scientific Experts*, U.S. FOOD & DRUG ADMIN. (Oct. 4, 2011), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm274351.htm>. As used here, a Special Government Employee

This lack of expertise results from: (1) high reviewer and manager turnover at CDRH (almost double that of FDA's drug and biologics centers); (2) insufficient training for staff; (3) extremely high ratios of front-line supervisors to employees; and (4) DRH's rapidly growing workload, caused by the increasing complexity of devices and the number of submissions under review.

In the Innovation Pathway, the FDA originally called for and undertook a pilot to create a vetted list of experts across two dozen membership organizations such as the American Academy of Neurology and the Society of Thoracic Surgeons.<sup>17</sup> It relied on membership in these professional associations to serve as a proxy for expertise without any means to "match" people to problems with any specificity. Although membership in the Society of Thoracic Surgeons might require that one practice as a thoracic surgeon, the list does not substitute for the ability to pinpoint expertise better on the basis of experience or even to ask people what kinds of problems they would like to work on. Above all, the vetted list does a poor job of reaching those with a great deal of know-how—for example, a Ph.D. candidate at a university whose dissertation is on a specific medical device, or an academic or doctor who does not belong to one of these groups.

### C. Diversity Deficit

The device-review process demands access to a diversity of expertise. Devices are very different (think of 3D printed exoskeletons versus heart-rate monitoring applications). Often, devices are cutting-edge, necessitating new kinds of expertise if they are to be reviewed adequately. As the FDA explains, devices are based on technologies that "combine many different fields, such as materials science, electrical engineering, [and] fluid mechanics."<sup>18</sup> And because new devices rely on new kinds of science, they are sometimes hard to describe and are often called by different names in different fields. This makes it even more challenging to identify a broad range of expert reviewers.

The agency is also responsible for keeping tabs on device safety from cradle to grave. It needs to know about a diversity of device types and industries, but also must be able to measure clinical, economic, and policy impact. This frequently demands different types of know-how. In addition, insight may be helpful from people in fields where one would not assume any prior knowledge.

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("SGE") is one who works for a term "not to exceed one hundred and thirty days during any period of three hundred and sixty-five consecutive days." See 18 U.S.C. § 202 (2012).

17. See *CDRH Network of Experts*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm289534.htm> (last updated Mar. 3, 2014).

18. Jessica Hernandez & Anjali Kataria, *FDA Profiles Project Description: Enabling New Models of Academia-Regulator Interactions: The Feasibility and Outcomes of Rapid Turnaround Consultation Processes*, Science of Science and Innovation Policy (SciSIP) Grant Application (unpublished manuscript at 2) (on file with author).



#### D. Complexity Deficit

As a result of the Innovation Pathway and some other measures, the backlog began to drop significantly in 2010.<sup>19</sup> But the gains are likely to be short-lived. A study completed by the Boston Consulting Group points to a rise in the number of drugs and complex devices approved in the European Union long before the United States. As devices get more complex, the United States is likely to fall further behind.<sup>20</sup> Although the FDA does not provide clear data on backlogs or processing times, research points to shortcomings within our current system for researching and approving complex devices. This has broad implications for the quality of care that Americans are receiving. For example, in 2011 the medical-device company Biosensors International shut down their operations in California due to the time and expense associated with getting FDA approval for a cardiac stent. The device is available in other countries, including in Mexico and Canada.<sup>21</sup>

The proliferation of mobile health devices such as heart monitors that leverage the sensors in a cellphone has further complicated the regulatory process and driven the demand for more knowledgeable and effective regulatory review. The Federal Communications Commission (FCC) regulates mobile devices and the FDA the medical devices.<sup>22</sup> The complexity of having to clear hurdles in two agencies led these agencies to conclude a Memorandum of Understanding in July 2010, promising to “improve the efficiency of the regulatory processes applicable to broadband and wireless enabled medical devices.”<sup>23</sup> But many feel progress has been too slow. In April 2012, six congressmen sent both the FDA and FCC a letter (at the behest of the mobile technology industry) urging the agencies to improve communication to avoid issuing “slow and inconsistent regulation” which might

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19. See *Improvements in Device Review: Results of CDRH's Plan of Action for Premarket Review of Devices*, U.S. FOOD & DRUG ADMIN. 12 (2012), <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM329702.pdf>.
  20. See Boston Consulting Group, *Competitiveness and Regulation: The FDA and the Future of America's Biomedical Industry*, CAL. HEALTHCARE INST., at iii (2011), <http://www.bcg.com/documents/file72060.pdf>.
  21. See Andrew Pollack, *Medical Treatment, Out of Reach*, N.Y. TIMES, Feb. 9, 2011, <http://www.nytimes.com/2011/02/10/business/10device.html>.
  22. See Fenwick & West Life Scis. Group, *The Regulatory Future of mHealth: FCC, FDA, and the United States Congress*, JD SUPRA BUS. ADVISOR (June 19, 2012), <http://www.jdsupra.com/legalnews/the-regulatory-future-of-mhealth-fcc-f-22552/>.
  23. Memorandum of Understanding Between the Federal Communications Commission and the Food and Drug Administration Center for Devices and Radiological Health 2 (July 2010), [http://www.elsevierbi.com/~media/Images/Publications/Archive/The%20Gray%20Sheet/36/031/01360310001/080210\\_fda\\_fcc\\_mou.pdf](http://www.elsevierbi.com/~media/Images/Publications/Archive/The%20Gray%20Sheet/36/031/01360310001/080210_fda_fcc_mou.pdf).

delay the progress of wireless medical technology.<sup>24</sup> The 2012 Food and Drug Administration Safety Innovation Act included a requirement that the FDA, FCC, and the Office of the National Coordinator in the White House publish a “proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.”<sup>25</sup>

### *E. Targeting Expertise to Accelerate and Improve Device Review*

New expertise platforms offer the promise of decreasing the cost of expressing and finding expertise, including better ways for assessing the identification of expertise, understood broadly to go beyond degrees received; searching for and finding relevant experts across multiple disciplines and institutions beyond those locally known to the searcher; and matching expertise to a hard problem (such as the steps involved in regulatory practices) with real-world consequences.

Sourcing expertise in highly technical fields where relevant expertise can also be found among academics and regulators, two populations who maintain data about their qualifications, is a natural first foray into expert networking. Academics regularly maintain data about their credentials and publications. The norms of the profession require sharing such information openly, and databases are already prevalent in the biomedical sciences than in other domains. Regulators are far less transparent about their credentials, but more so about their experience, at least internally. There is a record of which regulator worked on which regulatory action. In short, these are two groups about which data exists to aid in automating requests to participate.

There is no shortage of knowledgeable people in the biomedical sciences. In addition to the 800 scientists at CDRH, approximately 14,000 people work at the wider FDA,<sup>26</sup> and another 6000 scientists work at the National Institutes of Health (NIH).<sup>27</sup> There are over 83,000 employees at NIH’s parent agency, HHS,

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24. Letter from Marsha Blackburn et al., Members, U.S. Cong., to Margaret Hamburg, Comm’r, U.S. Food & Drug Admin. & Julius Genachowski, Chairman, U.S. Fed. Commc’ns. Comm’n (Apr. 3, 2012), [http://blackburn.house.gov/uploadedfiles/letter\\_from\\_congress\\_to\\_fda\\_and\\_fcc\\_-\\_3apr2012.pdf](http://blackburn.house.gov/uploadedfiles/letter_from_congress_to_fda_and_fcc_-_3apr2012.pdf); see Letter from Bradley Merrill Thompson, Member, Epstein Becker & Green, P.C., to U.S. Food & Drug Admin. (Oct. 11, 2012), <http://mhealthregulatorycoalition.org/wpcontent/uploads/2010/06/MRC-Comment-Letter-on-UDI-Proposal-10112012.pdf>.
  25. Food and Drug Administration Safety and Innovation Act, Pub. L. No 112-144, § 618, 126 Stat. 993, 1063 (2012).
  26. See *Distribution of Full-Time Equivalent Employment Program Level*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM301553.pdf> (last visited Apr. 18, 2014).
  27. See *About NIH*, NAT’L INST. HEALTH, <http://www.nih.gov/about/> (last visited Apr. 18, 2014).

not to mention the hundreds of thousands of biomedical professionals working in industry and academia.<sup>28</sup> While the FDA has a Medical Devices Advisory Committee comprising eighteen panels of medical practitioners and industry experts representing consumer and industry interests,<sup>29</sup> the FDA has no way to quickly discover enough diverse individuals who possess relevant expertise to review applications. The FDA also needs to find private sector participants who might have deeper knowledge of an innovation. In order to enhance its research and regulatory activities and accelerate its review, the FDA needs to find internal experts to advise regulatory review panels. Subsequently, it also needs external experts to participate in review panels and educate the agency about new trends in medical devices, such as identifying the therapeutic benefits of 3D printing or nanotech.

#### IV. THE EXPERIMENT: OPENING REGULATORY REVIEW WITH FDA PROFILES

Enter FDA Profiles. OSEL is launching this “Research Networking” software pilot under the leadership of one of FDA’s new “Entrepreneurs in Residence”—outside experts invited to do a stint in public service to inject innovative ideas and insights into government. These Entrepreneurs in Residence were given the mission of helping CDRH transform and accelerate the device-approval process. The original project lead was Anjali Kataria, who headed the Health Information and Decision Systems Program at the University of Maryland’s business school and who was asked to bring this experience to bear in implementing the Profiles project at the FDA.

Although unique in government, FDA Profiles is not revolutionary; it does not seek to upset the apple cart of power and change who makes the ultimate decisions at the FDA about devices. To the contrary, the project’s ultimate goal is to inform regulators about relevant experts more quickly. FDA Profiles uses the Harvard Profiles Research Networking Software (RNS) platform, developed by Harvard Medical School with support from the NIH. The platform is in use at 240 institutions, including Harvard, Penn State, Boston University, the University of California – San Francisco (UCSF) and more.<sup>30</sup> Profiles is an open-source expert discovery and networking tool that helps to find researchers with specific areas of expertise. “Profiles RNS imports and analyzes ‘white pages’ information, publications, and other data sources to create and maintain a complete searchable library of web-based electronic CV’s.”<sup>31</sup>

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28. See *2011 Strategic Sustainability Performance Plan*, U.S. DEP’T OF HEALTH & HUM. SERVS. 4 (2011), [http://www.hhs.gov/about/sustainability/2011plan\\_summary.pdf](http://www.hhs.gov/about/sustainability/2011plan_summary.pdf).

29. See *Advisory Committees*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/> (last updated Nov. 14, 2012).

30. See *Open Source Community*, HARVARD CATALYST, <http://profiles.catalyst.harvard.edu/?pg=community> (last visited Apr. 4, 2014).

31. See *id.*

The FDA Profiles pilot project is slated to launch in 2014 and create a searchable online expert directory, initially of FDA staff and then of outside scientists, using both internal FDA data such as personnel data and external data sources such as publications from PubMed and Web of Science. The goal of the first phase of the project is to test the speed and efficacy of using networking tools to improve collaboration between internal FDA scientists and regulators. Eventually, the goal is to enhance collaboration between government regulators and academia to improve the understanding of the complex science needed to make hard policy decisions.<sup>32</sup>

## V. HOW PROFILES MEASURES EXPERTISE

Harvard Catalyst Profiles measures expertise through a combination of passive and active means. In a form of passive networking, its expertise algorithms are designed to automatically add data from online publication sources to a person's Profiles bio and then to analyze this data to build a catalog of people's expertise and their research networks.<sup>33</sup> Passive networks are automatically created based on current or past co-authorship history, organizational relationships, and geographic proximity. Profiles can auto-populate a profile by scraping from online biographies, professional society memberships, education and training records, affiliations, regulatory accomplishments, publications from open databases, and grants from grants.gov.

In addition, in a form of active networking, a researcher can also manually add data about their interests, skills, and projects or specify their relationships with an advisor, mentor, or other people, "expand[ing Profiles] content with information about social networks that only they know."<sup>34</sup> With the combination of passively gleaned and actively contributed data, Harvard Catalyst Profiles speeds the process of locating the "right" experts by algorithmically matching people to opportunities to participate.

The organizing framework for all this data—whether scraped from databases or manually inputted—is borrowed from VIVO, another open-source expert discovery initiative. VIVO is a multi-university collaboration that represents authoritative data about researchers.<sup>35</sup> "When installed and populated with researcher interests, activities, and accomplishments, [VIVO] enables the discovery

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32. Telephone Interview with Jessica N. Hernandez, FDA Profiles Team Member (Mar. 31, 2014).

33. See Anjali Kataria, Food & Drug Admin. Entrepreneur in Residence, and Jessica N. Hernandez, Program Analyst, Office of Sci. and Eng'g Laboratories, Food & Drug Admin., Presentation on the OSEL Research Networking Software Pilot (Oct. 1, 2013).

34. *Professional Networking and Expertise Mining for Research Collaboration*, HARVARD CATALYST, <http://profiles.catalyst.harvard.edu/> (last visited Apr. 26, 2014).

35. Dean Krafft et al., *Enabling National Networking of Scientists*, 2010 WEB SCIENCE CONF., [http://journal.webscience.org/316/2/websci10\\_submission\\_82.pdf](http://journal.webscience.org/316/2/websci10_submission_82.pdf).

of research and scholarship across disciplines at that institution and beyond. VIVO supports browsing and a search function, which returns faceted results for rapid retrieval of desired information.”<sup>36</sup>

VIVO working groups have developed an ontology<sup>37</sup>—on which Harvard and FDA Profiles rely—for describing a researcher and her expertise. The ontology provides the organizing categories and common definitions for describing research fields, research projects, datasets used, teaching experience and, of course, fields of expertise. The Profiles tools use the VIVO ontology.

Profiles is designed to combine techniques of passive networking and active networking. From both of these sources, Profiles generates a set of prioritized keywords—the Concept Cloud—to define a researcher’s interests over time.<sup>38</sup>

People will be able to add their own skills and edit their own profiles. The Profiles platform uses an algorithm to return relevant search results in a list and in various visual graphs showing relationships between people. Type in “stent,” and FDA Profiles will list people at the FDA with explanations of why they were suggested in order to provide information that is useful in obtaining a technical consultation for a regulatory review in its first phase. Although Profiles will initially function as a kind of FDA/HHS Facebook, the plan is to connect with other networks like VIVO to find expertise outside the agency. In the future, there are plans to incorporate patents, as well as data from LinkedIn, SlideShare, and other social media, into FDA Profiles. There are also plans to integrate collaboration software with the people-search capacities of Profiles. Once one finds relevant experts, it is important to be able to communicate and collaborate with them. UCSF, for example, is experimenting with “Open Proposals,” a crowdsourcing site designed to engender pre-competitive collaboration among academics. It is generating robust and productive engagement.<sup>39</sup>

## VI. DOES TARGETING EXPERTISE WORK? TESTING THE HYPOTHESIS WITH CONTROLLED TRIALS

Whether left or right, governance practices often seem designed, as *New York Times* columnist David Brooks once said, by “people hermetically sealed in the house of government.”<sup>40</sup> We have policy walls in place that limit experimentation and diversity in policymaking practices. Software entrepreneur and political commentator Jim Manzi writes in *Uncontrolled: The Surprising Payoff of Trial-*

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36. About, VIVO, <http://www.vivoweb.org/about> (last visited Apr. 4, 2014).

37. See *Semantic Modeling of Scientist: The VIVO Ontology*, VIVO, <http://vivoweb.org/files/SemanticModeling.pdf> (last visited Apr. 4, 2014).

38. See *About Harvard Catalyst Profiles*, HARVARD CATALYST, <http://connects.catalyst.harvard.edu/Profiles/about/default.aspx> (last visited Apr. 17, 2014).

39. See *About UCSF Open Proposals*, UCSF OPEN PROPOSALS, <https://open-proposals.ucsf.edu/> (last visited Apr. 14, 2014).

40. David Brooks, *The Progressive Shift*, N.Y. TIMES, March 18, 2013, <http://www.nytimes.com/2013/03/19/opinion/brooks-the-progressive-shift.html>.

*and-Error for Business, Politics and Society*, his paean to the importance of the scientific method, that we lack the opportunity in policymaking “to experiment and discover workable arrangements through an open-ended process of trial and error.”<sup>41</sup> It is inexcusable, he laments, that we make macroeconomic decisions with global consequences with no means to know what works and why. He argues for freedom to experiment with different regulatory rule-sets at the most local level. This Jeffersonian brand of federalism is an intuitively appealing way to test what works. Although typically advocated by those on the right, critics like communications scholar Jonathan Taplin have also been articulating a federalist vision from the left.<sup>42</sup>

David Halpern, Senior Advisor to several recent British Prime Ministers, fought to establish a Social and Behavioural Insights (or “Nudge”) Unit in the Cabinet Office to advise the government on the use of randomized-controlled trials (RCTs) in policymaking in Britain. Randomized-control trials are used in medicine, business, and other fields to test effectiveness by comparing the outcomes of an intervention against a randomly selected group that does not receive the intervention. They are an inexpensive way to know what works when and where.<sup>43</sup> In a randomized control trial, the target population is divided at random into two groups, with different interventions applied to each. As noted earlier, what is standard practice among companies testing drugs or the design of a website is almost unknown in public policy where a mindset that the professionals know best still prevails.

What these social and behavioral experiments in government do not do, at least to date, is to experiment with approaches to *making policy* by comparing outcomes that result with and without different forms of public engagement. Choosing to vary where and how we restrict abortion or legalize prostitution and whether we make decisions at the federal or state level still fails to question underlying assumptions about who makes policy and how we make it on these issues in the first place. Brandeis’s laboratories of democracy<sup>44</sup> might cook up different policy prescriptions but with the same institutional beakers and burners we have always used. There is simply no experience within government of making governing professionals themselves, as well as the way they work, the object of careful experimentation.

Now imagine if randomized controlled trials had been used with the Aristotle program. A person trying to solve a problem could have tried to find experts

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41. JIM MANZI, *UNCONTROLLED: THE SURPRISING PAYOFF OF TRIAL-AND-ERROR FOR BUSINESS, POLITICS AND SOCIETY* xii (2012).

42. See Jon Taplin, *New Federalism Revisited*, JON TAPLIN’S BLOG (Sept. 21, 2011), <http://jontaplin.com/2011/09/21/new-federalism-revisited/>.

43. See Laura Haynes et al., *Test, Learn, Adapt: Developing Public Policy with Randomised Controlled Trials*, CABINET OFFICE BEHAV. INSIGHTS TEAM (2012), [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/62529/TLA-1906126.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/62529/TLA-1906126.pdf).

44. See *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandies, J., dissenting).

using traditional methods such as querying their own rolodex, and compared their results against using Aristotle to find experts. They then could have repeated this test many times. The DOD could have run similar tests, comparing the use of LinkedIn against the use of its internal system. Observing the differences could have yielded real insight. Imagine if half the target population at the DOD had their information automatically uploaded, and the other half was asked to fill out a form. It would be easy to compare results and see which approach yielded more useful profiles. Imagine if, when asking people to fill out the form, some people had been asked to share their credentials and others asked to say something about their skills. Who would be more likely to participate? And who, when later contacted with a request, would be more likely to answer? We will never know.

We are witnessing new strategies for combining human with machine intelligence<sup>45</sup> to organize knowledge. But there is still surprisingly little research on how complex organizations actually make decisions and solve problems using crowdsourcing and almost nothing on how they might combine crowdsourcing, with expert discovery. There is almost no empirical testing of alternatives in real-world contexts. White House innovation expert Tom Kalil is fond of saying that the Department of Education gives away two-thirds of its budget in grants and loans for education, but none of that money goes to experiment with learning how to create a Department of Education that works better.

The FDA Profiles project offers an early opportunity to gather empirical evidence about whether targeting expertise helps the agency overcome the challenges I have identified, including the agility deficit and the expertise deficit, and does so despite budgetary challenges. The agency itself, together with collaborators at UCSF, drafted a research proposal for studying whether “the new tools and processes to enable discovery of experts and their networks and facilitate conversations online might change how easily and fluidly a regulator such as the FDA and its community of experts might interact with academic scientists.”<sup>46</sup> The hypothesis, naturally, is that these tools will enable the kind of expertise sharing that is useful and relevant to the regulatory process.

As we test the efficacy of this innovation for improving how we make policy, we can advance our own understanding of whether targeting helps to increase intelligence in the system and of how institutions get smarter. FDA Profiles affords a chance to study the impact of expert networking on crowdsourcing more generally. But this will require introducing testing (including randomized controlled trials), such as comparing a general call to advise or participate in a regulatory review panel against attracting participation using Profiles. Doing so will advance our understanding of how to introduce approaches to policymaking that are both empirically validated and agile in design.

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45. For more on the advances resulting from the combination of human and machine intelligence today, see CLIVE THOMPSON, *SMARTER THAN YOU THINK: HOW TECHNOLOGY IS CHANGING OUR MINDS FOR THE BETTER* (2013).

46. Telephone Interview with Anjali Kataria and Jessica N. Hernandez, FDA Profiles Team Members (Aug. 8, 2013).

Introducing empirical research into FDA Profiles is a chance to experiment not simply with policies but also with the policymaking process. Even without changes to the current design of the FDA Profiles project, it would be possible to compare outcomes between regulatory review panels recruited and run with and without targeting. So, for example, even within the target populations of FDA or HHS personnel or biomedical academics that the profiles team will seek to upload into its database, it would be possible to compare targeting participation with Profiles against status quo methods to understand the impact of sorting by academic degree and publication. Does targeting on the basis of academic credentials have the downside of reaching those who are too busy to help and the whose professional norms discourage such volunteer activity?

Even more learning becomes possible if the project is adapted to build in opportunity for experimentation. After comparing the use of Profiles against its absence, experimenters could run parallel trials with tweaks to the algorithm. If first we want to test the impact of targeting, next we ought to test different ways of targeting.

For example, we might be able to sort people based on their degrees or their publication record but not both. We might also ask people to complete a questionnaire to assess their skills and experience, enabling a comparison between targeting based on skills and credentials and publications. We could take the same population in the Profiles database—a known and circumscribed group—and create new databases about their expertise by scraping data about them from other sources, such as LinkedIn, Facebook, and Wikipedia. We want to understand the impact of targeting based on traditional academic criteria, but good academics might turn out to be bad participants because they are trained to contribute in ways that are unhelpful to regulators (for example, academics used to writing long articles are often the least useful to busy government professionals). But testing a variety of criteria for selection should be a part of the rollout plan.

There is direct precedent for experimentation “in the wild” in institutional innovation, including using expert networking, in the experiments run by Professor Karim Lakhani and his colleagues. Lakhani, an expert in open-innovation practices, studied the impact of open innovation from the Harvard Catalyst project on diabetes research.<sup>47</sup> Harvard Catalyst is a “pan university clinical translational science center”<sup>48</sup> situated at Harvard Medical School exploring the question of how to rethink all aspects of the scientific-research process. To the end of solving “high-risk, high impact problems in human health-related research,”<sup>49</sup> Catalyst takes each aspect of the research process and designs a strategy for opening it up to more information and input from a wider audience. The goal is to bring in fresh ideas and novel perspectives.

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47. Eva Guinan, Kevin J. Boudreau & Karim R. Lakhani, *Experiments in Open Innovation at Harvard Medical School*, 54 MIT SLOAN MGMT. REV. 45 (2013).

48. *Id.*

49. *Id.* at 46.



In 2010, Catalyst undertook an experiment to open up how universities generate research questions.<sup>50</sup> Typically, an academic decides on the direction for his or her lab. In an effort to generate new ideas from unlikely sources for promising approaches to fighting Type 1 diabetes *before* investing research funding, Catalyst sponsored a \$30,000 prize-backed challenge. The Catalyst challenge was unique because it didn't ask people to come up with answers as is typically the case in crowdsourcing projects. Rather, contributors supplied the questions. This enabled people to suggest ideas regardless of whether they had the resources to solve the problem they proposed. After six weeks, 150 research hypotheses were submitted, encompassing a broad range of approaches from different disciplines. The authors analyzed the subject matter of the submissions and found that they were "quite different from what existed in the literature and from the existing body of ideas under investigation within the Type 1 Diabetes research community."<sup>51</sup> The Leona Helmsley Trust put up one million dollars in grant funding at Harvard to encourage scientists to launch experiments based on these newly generated research questions.

In addition to normal advertising of the grant opportunity, Harvard Catalyst used Profiles to identify researchers whose record indicated that they might be particularly well suited to submit proposals. The Profiles system takes the PubMed-listed publications for all Harvard Medical School faculty members and creates a database of expertise based on a classification of their published papers. The topics of the experimental design proposals were matched to these classifications. "The intention was to move beyond the established diabetes research community and discover researchers who had done work related to specific themes present in the new research hypotheses but not necessarily in diabetes."<sup>52</sup>

In the end, the matching algorithm yielded over one thousand scientists who potentially had the knowledge needed to create research proposals for these new hypotheses. Harvard Catalyst then emailed these faculty members and announced the new funding opportunity. As in the public sector, this kind of targeted outreach is not common in biomedical research.

The outreach resulted in thirty-one Harvard faculty-led teams competing for funding, of whom twenty-three had been identified using Profiles. Of those, fourteen had no significant prior involvement in Type 1 diabetes research. In the end, seven proposals were funded with five of the lead investigators having not done any prior work in Type 1 diabetes. It is too soon to know the impact of this experiment for sufferers of the disease. Typical timelines for medical innovations

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50. *Congratulations to the Winners of the First Harvard Catalyst/InnoCentive Ideation Challenge: "What Do We Not Know to Cure Type 1 Diabetes?,"* HARVARD CATALYST (Sept. 29, 2010), <http://catalyst.harvard.edu/news/news.html?p=1966>.

51. Beth Simone Noveck, *Innovating the Innovation Process: Re-imagining University Research*, GOVLAB BLOG (June 5, 2013), <http://thegovlab.org/innovating-the-innovation-process-re-imagining-university-research/> (quoting interview with Karim Lakhani).

52. Guinan et al., *supra* note 47, at 50.

translating from bench to bedside are fifteen to thirty years. But the experiment did yield some exciting results:

The core insight driving Harvard Catalyst's experiments was that all stages of the previously narrow and fully integrated innovation system—from hypothesis generation to idea selection to execution—can be disaggregated, separated and opened to outside input. By opening up participation to nontraditional actors, Harvard Catalyst achieved its objectives of bringing in truly novel perspectives, ideas and people into an established area of research.<sup>53</sup>

To understand whether smarter governance improves the effectiveness and legitimacy of decisionmaking at the FDA, FDA Profiles—as the first major ExpertNet initiative—could and should be transformed into a research experiment. Doing so would pave the way for more such research on institutional innovation. This could help the policy and research community study strategies for identifying and matching expertise; defining and framing the call; creating incentives to participate; and developing institutional readiness.

## VII. IDENTIFYING AND MATCHING EXPERTISE: WHO PARTICIPATES

FDA Profiles has its own algorithms for identifying potential experts within the FDA and outside of it. By mining grants, publications, and bio-sketches, the Profiles approach differs significantly from previous procedures. In light of this fact, Profiles may enable us to explore a new set of questions, including how we can best identify expertise and whether these new approaches worked better or worse as means of encouraging quality participation. As of now, several important questions remain unanswered. There is no guarantee, for example, that targeting based on credentials will yield the “right” community of participants. In fact, the whole problem is that we don't know up front who and what we don't know. The success of crowdsourcing and open innovation is that these practices attract unexpected participants. In the Harvard Catalyst case, the search they did was broad, resulting in a thousand potential candidates, many of whom had no direct training in diabetes research.

Similarly, in the FDA context, we can and should try to search narrowly and broadly and see what results. Empirical experiment opportunities can provide answers to questions, such as:

- How does Profiles identify who knows what?
- How does Profiles target requests to participate and “match” people to opportunities?
- Who participated more readily and more usefully? In other words, are those with the know-how that Profiles defines as expertise more or less likely to participate and are they more or less likely to participate in ways that are helpful and relevant to

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53. *Id.* at 47-48.

regulators? This can be answered using randomized control trials to compare results against putting out a general inquiry or using a different platform, which quantifies expertise differently.

- How useful are these techniques for surfacing diverse experts? In other words, it might be simple to find people who work on heart stents but how do I match a materials scientist who works in another domain but might have relevant insights to share?

The FDA needs expertise at different stages of decision making, from identifying emerging trends such as 3D printing to reviewing a specific device such as a new stent. FDA Profiles affords a chance to study whether expert networking and targeting participation by those with specific kinds of expertise works better at different stages. Are these techniques more useful for staffing review panels or getting insights about next-generation devices or other policymaking activities? It would be advisable to introduce a control in the process, such as putting out general calls to participate via social media or the *Federal Register* and contrast with using Profiles. In addition, comparisons can be run by inviting different groups of people to participate in review panels, including those that Profiles scored as most and least relevant in a search.

#### VIII. INCENTIVES AND MOTIVATION: IF WE BUILD IT, WILL THEY COME AND WILL THEY STAY?

“People are drawn to participate because some psychological, social, or emotional need is being met. And when the need isn’t met, they don’t participate,” writes *Crowdsourcing* author Jeff Howe.<sup>54</sup> FDA Profiles is an opportunity to experiment with incentives for engagement in policymaking empirically, using the behavioral insights we have from other fields about why people sign up and what causes them to participate.

The FDA Profiles pilot will begin by searching only scientists internal to the FDA to perform technical consultations. Presumably, the rates of participation will be high as people are being asked to do something consistent with their job requirements and performance. In fact, they might be required to participate. But what happens when Profiles rolls out to the broader agency and the wider world? Before the roll out, it will be important to design the research protocols to apply to the experiment and test what incentives cause people to share their knowledge and expertise.

FDA Profiles is an instance where the rewards for engagement are intrinsic. Intrinsic rewards include such things as autonomy or the degree of freedom and

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54. JEFF HOWE, *CROWDSOURCING: HOW THE POWER OF THE CROWD IS DRIVING THE FUTURE OF BUSINESS* 288 (2008).

creativity allowed by the task;<sup>55</sup> being part of a community;<sup>56</sup> learning during the process of contributing;<sup>57</sup> and altruism.<sup>58</sup> For example, “tight engagement with the community was critical to the success of knowledge sharing within the Stack Overflow community.”<sup>59</sup> Wikipedia participants responded that contributing in and of itself created a sense of satisfaction.<sup>60</sup> When asked why they contribute to Wikipedia, respondents said to educate humanity and raise awareness (48.9%); the feeling of making a difference (17.78%); and to give back to the Wikipedia community (15.56%). This is not uncommon: 53% of developers surveyed were influenced by social motivations such as learning, sharing knowledge, participating in new forms of cooperation, and participating in the open source community.<sup>61</sup>

By contrast, the motivation to say “yes” and join and then to participate is sometimes impelled by extrinsic considerations, such as monetary reward or gains in reputation or recognition. For example, Stack Overflow keeps track of users’ participation by awarding points, which in turn are used as a measure of reputation in the community. But much of the literature on online Q&A sites, for example, suggests that while monetary incentives such as prizes might be relevant to entice people to start participating, social incentives, such as social interaction with contributors, lead to continuing participation.<sup>62</sup>

Here we have the chance to deepen our understanding of how different groups respond to diverse incentives. Do they respond to the compelling nature of the call or the opportunity to participate consistent with their expertise and know-how? Does the framing of the challenge matter more than how participation is structured and organized? Do people behave differently when a formal prize is offered as opposed to a free t-shirt or implicit gratification? How do competition and a leaderboard showing the most frequent or helpful panelists impact engagement?

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55. Nicolas Kaufmann et al., *More Than Fun and Money. Worker Motivation in Crowdsourcing - A Study on Mechanical Turk* (2011), [http://www.researchgate.net/publication/220894276\\_More\\_than\\_fun\\_and\\_money.\\_Worker\\_Motivation\\_in\\_Crowdsourcing\\_-\\_A\\_Study\\_on\\_Mechanical\\_Turk/file/9fcfd50e5afe007d78.pdf](http://www.researchgate.net/publication/220894276_More_than_fun_and_money._Worker_Motivation_in_Crowdsourcing_-_A_Study_on_Mechanical_Turk/file/9fcfd50e5afe007d78.pdf).

56. Stacey Kuznetsov, *Motivations of Contributors to Wikipedia*, ACM SIGCAS COMPUTERS & SOC’Y NEWSL., June 2006, at 4.

57. *Id.*

58. *Id.* at 3.

59. Lena Mamykina et al., *Design Lessons from the Fastest Q&A Site in the West*, 2011 PROC. SIGCHI CONF. ON HUM. FACTORS IN COMPUTING SYS. 2857, 2865.

60. Kuznetsov, *supra* note 56, at 3.

61. Rishab Aiyer Ghosh, *Understanding Free Software Developers: Findings from the FLOSS Study*, in PERSPECTIVES ON FREE AND OPEN SOFTWARE 23, 35 (Joseph Feller et al. eds., 2005).

62. See Mamykina et al., *supra* note 59.

In addition to assessing whether the nature of the reward causes or depresses participation, we want to look at how people behave when the incentives change. In one study of the use of badges on Stack Overflow, the authors found that certain users will essentially game the system—altering their behavior in order to maximize their potential to receive badges. This raises the question of whether and in what circumstances badge systems necessarily encourage high-quality contributions.<sup>63</sup> In another study of human motivation on social networks, the design of the interface and whether it publicly displayed user performance correlated positively with the volume of participation.<sup>64</sup>

FDA Profiles is an early chance to understand for the public sector:

- What are the extrinsic (rewards, points, badges, prizes) and intrinsic (altruism, autonomy, curiosity, empathy) motivations for participation, and how do they compare within the context of solving societal problems?
- How can a single call for participation cater to the heterogeneous motivations that may be necessary to engage the optimal variety of experts?
- Are there certain types of incentive structures that are better able to create a community of expert problem-solvers?
- How can institutions ensure that participants feel as though they are legitimate, albeit peripheral, participants in the innovation process, rather than free labor whose input can be thoughtlessly accepted or rejected?
- How can institutions ensure that citizens' input and efforts are useful within the segment of the population where open innovation's greatest incentive is the ability to self-select and choose what problems to work on and how?

Also, we want to understand when using expert networking and people search tools to target expertise offers a more cost-effective substitute or perhaps a complement to prizes. Prizes help to coax experts out of a broader population. With expert networking, perhaps prizes become superfluous. We want to explore through experimentation how they can be combined in ways that solve problems and build a useful directory of people available to solve problems over time.

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63. Ashton Anderson et al., *Steering User Behavior With Badges*, 22 PROC. INT'L CONF. WORLD WIDE WEB 95 (2013).

64. Al M. Rashid et al., *Motivating Participation by Displaying the Value of Contribution*, 2006 PROC. SIGCHI CONF. HUM. FACTORS COMPUTING SYS. 955.

## IX. READINESS AND IMPEDIMENTS

Designing a citizen-engagement program that yields results needs to focus on the motivation of the consulting institution as well as individual participants. Even if the agency can match experts, frame the problem, and create meaningful incentives to participate, it still has to be ready and able to use the know-how they contribute. This is where there is a dearth of research. How the expertise gets used offers another avenue for exploration, especially as there exists an opportunity to adjust how people engage consistent with statutory limitations. The effectiveness of targeting has to be measured in the context, for example, of whether the regulatory review panel meets online or offline, how often and under what rule system. For example, if the expertise being sought is requested online, there is a learning curve with new members that can impact the conversations taking place, as new people get up to speed. Users bring experience from other interactions to new platforms. An earlier study found that a user's outlook, moderation behavior, and replies to comments are key in continued participation. Variables affecting participation outcomes include previous experience, observation, and feedback.<sup>65</sup> In other words, experience with participation online, as opposed to subject matter expertise, might ultimately correlate better with performance. The way the agency uses the advice has to be considered when weighing how to use expertise.

The FDA experience with FDA Profiles will provide insight into the impediments that prevented the agency from making use of participant expertise. Did it face legal or cultural barriers when rolling out the project or using the input received? Others will be eager to know. How did it use the input? Who had to give permission or acquiesce to the adoption of the project? How were agency officials affected? What was their own view of the usefulness of the engagement?

When the need is identifying people to serve on regulatory approval panels, to review grants, or to serve on advisory committees, it is easy to imagine that the institution will find it easy to make use of a searchable directory of candidates to fill these pre-defined roles and answer clearly articulated regulatory questions. We have yet to confirm if this is true. Further research will also have to be undertaken to learn whether these techniques work just as well when the goals are different. For example, organizations often need quick access to missing facts from those likely to have them. At other times, however, the need is for diverse viewpoints from a wide array of sources. Often the need is for input from people belonging to specific groups, whether stakeholders or experts, in order to ensure the legitimacy of decisionmaking. We are only at the beginning of testing when and in which circumstances targeting expertise helps.

Assessment of FDA Profiles should pay close attention to the impact of providing certain experts with greater access and influence to how we govern.

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65. Cliff Lampe & Erik Johnston, *Follow the (Slash) Dot: Effects of Feedback on New Members in an Online Community*, 2005 PROC. INT'L ACM SIGGROUP CONF. ON SUPPORTING GROUP WORK 11, 11.

## CONCLUSION

In the context of device review, grant review, and other domains where expertise is clearly called for, it would seem that using expert networking platforms can only democratize what are currently fairly closed processes. Whether or not it will privilege a new audience, however, remains to be seen. It is still an open question how to use the same smarter governance tools and techniques in connection with more value-based rather than fact-based decisions.

CDRH is primed and eager for this project, and has a clear idea of the kind of expertise that is needed. But it needs to embrace experimentation as part of the process if we are to learn with any certainty how Profiles worked and whether it worked well enough to merit continued investment. The ExpertNet project offers the opportunity to test empirically whether segmenting and targeting the audience helps to improve participation.

The role of the regulator is fraught. Regulatory agencies are frequently under siege from industry groups who bemoan burdensome and costly requirements as impeding economic growth and the progress of innovation. At the same time, consumer groups assault them for failing to prioritize the public interest and protect citizens from dangerous and fraudulent products and services. Both sides challenge their ability to impose requirements, questioning whether authority has been properly delegated to them and whether their practices are legitimate. Both sides complain about a lack of effectiveness and inefficiency in how they work. The FDA has long come under heavy attack for failing to do its job well.

Traditionally, the approach to fixing the problem has been sought in Congress. Industry and consumer groups seek legislation to clarify the rules and requirements and impose procedures favorable to their point of view. The new law, in turn, delegates to the agency the power to make regulations pursuant to administrative law developed in the 1940s with limited opportunities for public consultation. We make these decisions in the same way we always have, making the legislative battlefield the place where disputes play out. No data is shared, and decisionmaking is done behind closed doors in order to protect corporate secrecy and safeguard the integrity of the process.

New technology has opened up new possibilities for changing how we make decisions that could improve both the effectiveness and legitimacy of how we regulate. The FDA Profiles pilot is also a radical experiment. It changes the default on how the agency makes decisions by bringing in diverse expertise at the outset (and has the potential to do more once it begins to get used outside the FDA). The hope is that, by finding the right experts and matching them to opportunities to participate, they can inform the work of the agency and lead to the making of better decisions faster. It remains to be seen whether opening up how the agency works will transform the effectiveness, legitimacy, and impact of the FDA's work.

But the FDA's willingness to *experiment* with projects like FDA Profiles potentially heralds a sea change in terms of a receptivity to expert networking and, perhaps more importantly, to empirical research to drive institutional innova-

tion. When social-science research is integrated with the practice of policymaking, we gain insight into the resulting impact on decisionmaking and people's lives. We can then apply what we learn to the broader goal of improving governance.